DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95019d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT 5 2004

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Jordan Metzgar
3TP LLC
33 Flying Point Rd. Suite 217
Southampton, New York 11968

Re: 3TP Software, K031350

Dear Mr. Metzgar:

The Diagnostic Devices Branch (DDB), Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your Internet website for 3TP Software. Based on our review of your website, it appears that your company is marketing 3TP Software for intended uses beyond the scope of your FDA clearance for the product.

3TP Software is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or because it is intended to affect the structure or any function of the body.

FDA cleared 3TP Software for the following indications:

> The 3TP Software Option is intended to be used as a post processing software package designed to provide a reliable means for visualizing the presence and pattern of contrast induced enhancement on MR datasets. 3TP supports the evaluation of dynamic MR data gathered during the injection of a bolus of contrast media. The resulting time course information can be displayed in a variety of formats, including a parametric image overlaid onto source MR images. In the hands of a trained physician the information provided by the 3TP Software Option could yield information that may assist in the interpretation of dynamic contrast enhanced studies.

Your website, http://vclassroom.hyperion.com, demonstrates that 3TP LLC is marketing the 3TP Software for intended uses that do not fall within the existing clearance. For instance, the website states that 3TP Software "facilitates rapid detection of breast cancer."

Other items on the website that go beyond your FDA clearance include:

- "There are various methods of detecting cancer using MRI technology, however, the patented 3TP technique is the only one that provides an accurate, scientific based standardized system."

- "3TP is an innovative software solution that facilitates detection of breast cancer through rapid interpretation of contrast enhanced MRI images."

Marketing the 3TP Software for indications beyond the scope of your FDA clearance violates the law. Specifically, the device is adulterated under section 501(f)(1)(B) of the Act because you do not have an approved Premarket Approval Application (PMA) to demonstrate that the device is safe and effective for the new intended uses for which you are marketing it. In addition, your device is misbranded under section 502(o) of the Act because you have not submitted a section 510(k) premarket notification to notify the agency of your intent to introduce the device into commercial distribution for these new intended uses. For a product requiring premarket approval, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the FDA. [21 CFR 807.81(b).]

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure promptly to correct these deviations may result in regulatory action against your company being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Also, federal agencies are informed about warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. William C. Maloney, Physicist, Diagnostic Devices Branch (HFZ-322), at the letterhead address.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health